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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,242	09/24/2003	Ann M. Lees	10797-004006	7827
26161	7590	07/21/2005	EXAMINER	
FISH & RICHARDSON PC			MITRA, RITA	
P.O. BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	

1653

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/671,242

Applicant(s)

LEES ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I        Claims 1-40, drawn to a method of identifying an agent that inhibits the binding of LBP-2 to an LBP-2 binding molecule by contacting *in vitro* an LBP-2 polypeptide, and a candidate agent and measuring the formation of a complex containing the LBP-2 polypeptide and the LBP-2 binding molecule, wherein the reduction in the formation of the complex in the presence of the candidate agent as compared within the absence of the candidate agent was determined; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group I be elected, applicants are required to select one amino acid sequence from SEQ ID NOs: 7, 19, 20, 21 22 and 43.

- II        Claims 41-66, drawn to a method of identifying a candidate agent that binds to an LBP-2 regulatory nucleic acid sequence by contacting *in vitro* a candidate agent and an LBP-2 regulatory nucleic acid sequence; and measuring the binding of the candidate agent to the LBP-2 regulatory nucleic acid sequence; classified in class 536, subclass 23.1, 23.5; class 435, subclass 6.

Should Group II be elected, applicants are required to select one amino acid sequence from SEQ ID NOs: 7, 19, 20, 21 22 and 43.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and invention II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of invention I is not used for the practice of invention II, and nucleic acid of II is not

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necessary for the practice of invention I, Therefore the inventions are distinct. Also inventions I and II require different steps and are directed to different ends and different effect. Therefore the inventions are distinct.

The restriction requires for a selection of a single sequence of polynucleotide sequence and a single sequence of amino acid sequence because each sequence has a different chemical and physical property (See specification pages 2 and 8). For example the human LBP-1, LBP-2 and LBP-3 nucleic acid molecule has the nucleotide sequence shown in Fig 22, 23 and 24 respectively; which are distinct from each other. Therefore, the use of each sequence in the method claims would have a different effect, for example use of a nucleic acid sequence from LBP-1 as a probe for the detection of nucleic acid in a sample may not detect the nucleic acid sequence of LBP-2 and/or LBP-3, similarly while use of a polypeptide sequence of LBP-1 for identifying a compound that specifically binds to the polypeptide of LBP-1 may not detect the compounds that bind with the polypeptide of LBP-2 and/or LBP-3. Therefore each sequence is distinct from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### *Inquiries*

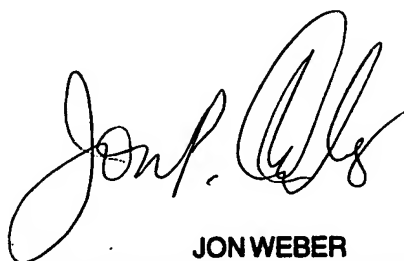
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The

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Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.  
July 15, 2005



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**